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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,568	05/15/2001	Samuel Bogoch	9425/46702	8438

7590 10/12/2006

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,568	BOGOCH, SAMUEL	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *6-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/12/06 has been entered.

Claims 1-13 are pending. Claims 1-5 are under examination.

The amendment to claims 1 and 5 is considered to be supported by para. [028] of the specification filed on 8/15/05, by para. [028] of the specification filed on 7/21/01, and by the para. spanning pp 16-17 of the specification filed on 5/15/01.

The amendment has overcome previously stated issues as follows:

The objection to the specification.

The rejection of claims 1-5 under 35 USC 112, 2nd paragraph.

The rejection of claims 1-5 under 35 USC 112, 1st paragraph, as set forth at p 3 of the action mailed 2/13/06.

The prior art rejections based upon Bogoch (4,976,957 or EP 0,015,078).

The prior art rejections based upon Bogoch in view of Chase.

The following ground(s) of rejection are maintained:

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The amended version of claims 1 and 5 has done nothing to overcome the lack of enablement found by the BPAI, in parent case 08/031,562 (see Paper 33 mailed 11/30/2000). The fact that applicant no longer uses the word "vaccine" does not overcome, since killing glioma cancer cells, as required by the claim is taken to involve a treatment that treats glioma cancer and that would be effective in increasing patient survival time. The mere fact that applicant has narrowed the scope of the claims to the

treatment of glioma cancer does not overcome; it is to be noted that the BPAI did address the invention as it pertains to glioma cells in rats (Paper 33 at page 12). Furthermore, the claims are presently more specific than those that were considered on appeal before the BPAI, in that the claims now require that administration of the malignin stimulate the production of cytotoxic antibodies. The disclosure has given no particular direction as to how one should conduct such an immunization, so as to particularly stimulate the production of cytotoxic antibodies, as opposed to the production of antibodies which do not have cytotoxic activity.

Applicant has submitted the Masui et al article to show that in vitro cell killing ability correlates with in vivo cell killing ability. This reference is irrelevant to the instant claims. First, the reference shows a toxin conjugated monoclonal antibody against cancer cells. The cancer cells are thus killed by the action of the conjugated toxin, rather than by any cytotoxic capability of the antibody component of the conjugate per se. Second, the article merely shows a in vivo model system which is not representative of treating an established glioma cancer in a subject. Third, the article would not even remotely show one of skill how to vaccinate/immunize an individual so that cytotoxic antibodies against cells bearing the immunogenic component of the vaccine.

Applicant's arguments filed 7/12/06 have been fully considered but they are not persuasive for the above reasons.

Applicant's amendment has necessitated the following new ground(s) of objection.

The disclosure is objected to because of the following informalities: At page 12, in para [029], the current status of application 07/744,649 must be indicated.

Appropriate correction is required.

The following new ground(s) of rejection are stated:

Claim 5 is rejected under 35 U.S.C. 102(b anticipated) as being anticipated by Bogoch (4,840,915).

Bogoch teaches that malignin can be extracted from glioma cells. See col. 2, lines 42-50; col. 13, line 45-col. 16, line 68; and col. 17, lines 8-12 and 64-67. Instant claim 5 recites "for killing..." which is merely an intended use. Therefore, the composition of malignin itself anticipates. The phrase "effective dosage" adds no weight, since the amount that is "effective" will depend upon numerous variables, such as the route of administration, the kind of adjuvant used, etc. Even if weight were given to the phrase "effective dosage", the reference would clearly anticipate because it teaches "1mg of MALIGNIN" at col. 16, line 68. This is precisely the amount that applicant considers to be an "effective dosage" as shown by instant claim 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 10/2/06 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 162

1644